REMARKS

Claims 18-39 are pending. Claims 18-39 are amended. As amended, the claims clarify that the claims are directed to a lipolytic enzyme composition in which the lipolytic enzyme composition has an average of two or three covalently linked non-amino acid hydrophobic groups per molecule. The amendments to the claims are supported by the specification at page 5, lines 10-12, describing covalently linking on average 2 to 3 hydrophobic groups to each enzyme molecule, and page 4, describing various non-amino acid hydrophobic groups.

The specification has been amended to correctly recite the tradename LIPOLASE®.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 18-39 under 35 U.S.C. 112

Claims 18-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, as follows.

The use of the phrase "modified by having two or three" in claim 18, and "has an amino acid sequence having two or three" in claims 19 and 25 is rejected as indefinite and confusing because it is asserted that "having" in both phrases has two meanings. As amended, the claims now clarify that the lipolytic enzyme composition has on average 2-3 hydrophobic groups per lipolytic enzyme. Thus, Applicants respectfully submit that the rejection is rendered moot.

Claim 24 is rejected as incomplete on the basis that it omits an essential step. The Examiner states that the missing essential steps are (a) treating a lipase with a derivatizing agent and (b) purifying the derived lipase from the reaction mixture. As used in claim 24, the phrase "covalently linking" encompasses the steps of preparing the lipolytic enzyme for addition of the two or three hydrophobic groups, and would include adding any derivatizing and purifying the lipase, if necessary.

The phrase "change number and/or position" in claim 30 is asserted to render the claim indefinite on the basis that these terms are redundant. Applicants respectfully submit that the term "number" is not redundant with the term "position." As used in the claim, the term "number" refers to how many amino, thiol, hydroxyl or carboxy groups are located in the lipolytic enzyme whereas the term "position" refers to where the amino, thiol, hydroxyl or carboxyl groups are located in the lipolytic enzyme. Thus, the phrase "change number and/or position" therefore does not render the claim indefinite because the two terms can be distinguished.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 18, 21-23, 24, 27-29 and 36 under 35 U.S.C. 102(b) over WO 92/05249

Claims 18, 21-23, 24, 27-29 and 36 are rejected under 35 U.S.C. 102(b) over WO 92/05249.

As amended, the claims clarify that the hydrophobic groups are non-amino acid hydrophobic groups, such as, fatty acyl groups, attached via covalently linkages to an amino group, a thiol group, a hydroxyl group or a carboxyl group of the lipolytic enzymes. WO 92/05249 does not disclose such non-amino acid modifications, rather WO 92/05249 is directed to amino acid deletions or substitutions, generally prepared by altering the encoding DNA. Although the resulting amino acid sequence may be suitable for the claimed modifications, the claimed modifications have not been applied.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 18, 21-23, 24, 27-29 and 36 under 35 U.S.C. 102(e) over U.S. Patent No. 5,869,438

Claims 18, 21-23, 24, 27-29 and 36 are rejected under 35 U.S.C. 102(e) over U.S. Patent No. 5,869,438.

As amended, the claims clarify that the hydrophobic groups are non-amino acid hydrophobic groups, such as, fatty acyl groups, attached via covalently linkages to an amino group, a thiol group, a hydroxyl group or a carboxyl group of the lipolytic enzymes. U.S. Patent No. 5,869,438 does not disclose such non-amino acid modifications, rather U.S. Patent No. 5,869,438 discloses mutagenizing the amino acid sequence, generally prepared by altering the encoding DNA. Although the resulting amino acid sequence may be suitable for the claimed modifications, the claimed modifications have not been applied.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102(e). Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 18-20, 23-26 and 29 under 35 U.S.C. 102(b) or 103(a)

Claims 18-20, 23-26 and 29 are rejected under 35 U.S.C. 102(b) as anticipated or, in the alternative, obvious over any of Murakami et al., Basri et al. and Inada et al. This rejection is respectfully traversed.

Murakami et al. disclose a lipase that has 12 amino groups (11 lysine + N-terminal) and the chemical modification ratio is 38-81%, resulting in 4.6 to 9.7 chemical hydrophobic groups per molecule. Thus, Murakami et al. does not anticipate the claimed invention, which claims a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule. There is also no motivation in Murakami et al. to covalently link fewer hydrophobic groups to the lipase.

Basari et al. disclose the amino acid sequence of *Candida rugosa* lipase (such lipase is disclosed at http://molbio.info.nih.gov/cgi-bin/moldraw?1CRL, attached as Exhibit 1), which has 21 amino groups (20 lysine + N-terminal), and the chemical modification is 32-91%, resulting in 6.7 to 19.1 chemical hydrophobic groups per molecule. Thus, Basari et al. does not anticipate the claimed invention, which claims a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule. There is also no motivation in Basari et al. to covalently link fewer hydrophobic groups to the lipase.

Inada et al. discloses a *Pseudomonas fluoresecense* lipase (two of such lipases are disclosed at http://ca.expasy.org/cgi-bin/sprot-search-ac?LIPA_PSEFL and http://ca.expasy.org/cgi-bin/niceprot.pl?P41773, attached as Exhibits 2 and 3), having 17 (16 lysine + 1 N-terminal) and 21 (20 lysine + 1 N-terminal) amino groups, respectively. The reference describes a 52% modification of amino groups resulting in 8.8 to 11.4 hydrophobic groups. Thus, Inada et al. does not anticipate the claimed invention, which claims a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule. There is also no motivation in Inada et al. to covalently link fewer hydrophobic groups to the lipase.

For the foregoing reasons, Applicants submit that the claims overcome this rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claims 21, 22, 27 and 28 under 35 U.S.C. 103(a)

Claims 21, 22, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boel et al. in view of any of Murakami et al., Basri et al. and Inada et al. This rejection is respectfully traversed.

Murakami et al., Basri et al. and Inada et al. are cited as discussed above. Boel et al. is cited as disclosing the cloning of *H. lanuguinosa* lipase, which is stated to have 7 lysine residues and one N-terminus. There is no motivation to substitute the lipase of Boel et al. for the lipases of Murakami et al., Basri et al. or Inada et al.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 18-33 and 35-39 under 35 U.S.C. 103(a)

Claims 18-33 and 35-39 are rejected under 35 U.S.C. 103 as being unpatentable in view of Svendsen et al., U.S. Patent No. 5,869,438, in view of Murakami et al., Basri et al., Inada et al. and Olesen et al.

As previously discussed, Murakami et al., Basri et al., Inada et al. do not disclose a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule. There is also no motivation in Murakami et al., Basri et al., Inada et al. to covalently link fewer hydrophobic groups to the lipase. Though not cited by the Examiner for this purpose, the addition of Svendsen et al. and Olesen et al. do not cure the deficiencies of either of Murakami et al., Basri et al., and Inada et al.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. The Rejection of Claims 18-30. 31. 33 and 35-39 under 35 U.S.C. 103

Claims 18-30, 31, 33 and 35-39 are rejected under 35 U.S.C. 103 as being unpatentable in view of Svendsen et al., WO 92/05249, in view of Murakami et al., Basri et al., Inada et al. and Olesen et al.

As previously discussed, Murakami et al., Basri et al., Inada et al. do not disclose a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule. There is also no motivation in Murakami et al., Basri et al., Inada et al. to covalently link fewer hydrophobic groups to the lipase. Though

not cited by the Examiner for this purpose, the addition of Svendsen et al. and Olesen et al. do not cure the deficiencies of either of Murakami et al., Basri et al., and Inada et al.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VIII. Double Patenting

Claims 18-33 and 35-39 are rejected under for obviousness-type double patenting over Claims 1-51 of US. Patent No. 5,869,438 in view of Murakami et al., Basri et al., Inada et al. and Olesen et al.

This rejection is respectfully traversed. As previously discussed, the claimed invention is patentably distinct over U.S. Patent No. 5,869,438 in view of Murakami et al., Basri et al., Inada et al. and Olesen et al. as these references do not disclose a modified lipolytic enzyme composition (and methods of producing) which has an average of two or three hydrophobic groups per lipolytic enzyme molecule.

Applicants respectfully requested reconsideration and withdrawal of the obviousness-type double patenting rejection.

IX. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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